

SUNSTATION ALL-NATURAL SPF 30 SUNSCREEN- titanium dioxide, zinc oxide lotion
Sunstation USA, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Sunstation All-Natural SPF-30 Sunscreen

Drug Facts:

Active Ingredients

Titanium Dioxide 6.00%

Zinc Oxide 6.00%

Purpose

Sunscreen

Uses:

- Helps prevent sunburn.
- If used as directed with other sun protection measure (see directions), decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings

- For external use only.

Do not use

on damaged or broken skin.

When using this product

keep out of eyes. Rinse with water to remove.

Stop use and consult physician if

irritation or rash develops.

Keep out of reach of children.

If product is swallowed, get medical attention or contact poison control center immediately.

Directions:

- Apply liberally 15-minutes before sun exposure

Reapply:

- At least every two-hours.
- Immediately after swimming, sweating or towel drying.

SUN PROTECTION MEASURES: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use sunscreen with broad spectrum protection and an SPF rating of 15 or higher, along with other sun protection measures including:

- Limit time in the sun, especially between 10am and 2pm.
- Wear long sleeve shirts, pants, hats and sunglasses.
- For children under 6-months, consult a physician.

OTHER INGREDIENTS:

Aloe Barbadensis (Aloe Vera Gel) juice, Aqua (Deionized Water), Butyrospermum Parkii (Shea) Butter, Camellia Sinensis (Green Tea) Extract, Cocos Nucifera (Coconut) Oil, Dehydroxanthan Gum, Gluconolactone, Glycerin, Glycine Soja (Soybean) Oil, Helianthus Annuus (Sunflower) Oil, Lecithin, Mangifera Indica (Mango) Butter, Sodium Benzoate, Sodium Laurylglucosides Hydroxypropylsulfonate, Styrene/Acrylates Copolymer, Tocopheryl (Vitamin E), Xanthan Gum

OTHER INFORMATIONS:

- Protect this product from excessive heat and direct sunlight.

Package Labeling:

SUNSTATION^{USA}

**ALL-NATURAL SPF-30 BROAD SPECTRUM - WATER RESISTANT (80 MINUTES)
100% REEF FRIENDLY - UVA/UVB PROTECTION SUNSCREEN**

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Sunstation USA, St. Louis, MO 63101

MADE IN THE USA

SUNSTATIONUSA.COM



SUNSTATION ALL-NATURAL SPF 30 SUNSCREEN

titanium dioxide, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71272-811
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	60 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	60 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0K00R)	
SHEA BUTTER (UNII: K49155WL9Y)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
COCONUT OIL (UNII: Q9L0O73W7L)	
DEHYDRO XANTHAN GUM (UNII: 63ZP711BQO)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
GLYCERIN (UNII: PDC6A3C0OX)	
SOYBEAN OIL (UNII: 241ATL177A)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
MANGO (UNII: I629IBNR86)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71272-811-01	1000 g in 1 CONTAINER; Type 0: Not a Combination Product	02/28/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/28/2017	

Labeler - Sunstation USA, LLC (080497172)